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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PROCESSING IN WATER IN STILL RETORTS

(Retort Survey)

INSTRUCTIONS

Complete the question blocks below. Draw a diagram of the retort or obtain one from the firm and attach it to the EIR as an exhibit. Report all pipe sizes as inside diameter (ID). Cross-sectional area = $3.14r^2$ (r = ½ diameter).

If problems are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response," and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance." Submit the completed form as an EIR attachment.

RETORT DESCRIPTION

RETORT NO.	TYPE OF RETORT	LENGTH OR HEIGHT	DIAMETER
	Vertical ☐ Horizontal ☐		

NUMBER OF BASKETS OR CRATES PER RETORT:

FOR VERTICAL RETORTS, BOTTOM CRATE SUPPORTS ARE PRESENT TO PROTECT THE STEAM SPREADER. Yes ☐ No ☐

*(**SHALL** REQUIREMENT, 113.40(b)(6))*

ARE BAFFLE PLATES PRESENT IN THE BOTTOM OF RETORT? ..... Yes ☐ No ☐

*(BAFFLE PLATES **SHALL** NOT BE USED, 113.40(b)(6))*

ARE VERTICAL RETORTS EQUIPPED WITH CENTERING GUIDES TO PROVIDE A 1.5-INCH CLEARANCE BETWEEN THE SIDE WALLS OF THE RETORT AND THE CRATE? ..... Yes ☐ No ☐

(SHOULD REQUIREMNT – 113.40(b)(6)

ARE THERE ANY PROTRUSIONS INSIDE THE RETORT OR THE RETORT DOOR CASING WHICH COULD DAMAGE CONTAINERS DURING LOADING/UNLOADING OF CRATES? ..... Yes ☐ No ☐

DO THE RETORTS FOLLOW THE ARRANGEMENTS IN THE DIAGRAM FOUND IN 113.40(b)(13)? ..... Yes ☐ No ☐

IF NO, DOES THE FIRM HAVE ON HAND HEAT DISTRIBUTION DATA OR OTHER SUITABLE INFORMATION THAT DEMONSTRATES THAT THE HEAT DISTRIBUTION IS ADEQUATE? ..... Yes ☐ No ☐

EXPLAIN, IF NECESSARY:

(SHALL REQUIREMENT OF 13.40(b)(13))

COMPUTER CONTROLS

DOES A COMPUTER CONTROL ANY OF THE RETORT FUNCTIONS? ..... Yes ☐ No ☐

DOES THE FIRM HAVE DOCUMENTATION ON HAND THAT INDICATES THAT THE COMPUTER SYSTEM HAS BEEN VALIDATED? Yes ☐ No ☐

EXPLAIN:

IS RECORD KEEPING PART OF THE COMPUTER FUNCTION? ..... Yes ☐ No ☐

IF YES, DOES THE RECORD KEEPING COMPLY WITH 21CFR PART 11? ..... Yes ☐ No ☐

EXPLAIN:

INDICATING MERCURY IN-GLASS THERMOMETERS (113.40(b)(1))

IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER ..... Yes ☐ No ☐

(SHALL REQUIREMENT)

IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATOR? ..... Yes ☐ No ☐

IF YES, DESCRIBE THE TEMPERATURE INDICATOR:

ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)? ..... Yes ☐ No ☐

(SHALL REQUIREMENT)

NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: _____. *(TEMP. RANGE MUST NOT EXCEED 17°F (8°C PER INCH (4°C/ CM) OF GRADUATED SCALE – SHALL REQUIREMENT. SEE LACF GUIDE-PART 2.)*

DATE LAST TESTED FOR ACCURACY:

*(THERMOMETERS **SHALL** BE TESTED FOR ACCURACY AGAINST A KNOWN ACCURATE STANDARD THERMOMETER UPON INSTALLATION AND AT LEAST ONCE A YEAR THEREAFTER; RECORDS OF ACCURACY CHECKS THAT SPECIFY DATE, STANDARD USED, METHOD USED, AND PERSON PERFORMING THE TEST SHOULD BE MAINTAINED. EACH THERMOMETER SHOULD HAVE A TAG, SEAL, OR OTHER MEANS OF IDENTITY THAT INCLUDES THE DATE IT WAS LAST TESTED FOR ACCURACY.)*

STANDARD USED FOR THE TEST:

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER? ..... Yes ☐ No ☐

WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED? ..... Yes ☐ No ☐

(SHOULD REQUIREMENT)

DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS WHICH WERE OUT OF CALIBRATION:

IS THE MERCURY UNDIVIDED? ..... Yes ☐ No ☐

*(A THERMOMETER THAT HAS A DIVIDED MERCURY COLUMN OR THAT CANNOT BE ADJUSTED TO THE STANDARD **SHALL** BE REPAIRED OR REPLACED (113.40(b)(1).)*

WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS? ..... Yes ☐ No ☐

DESCRIBE THE FIRM'S PROCEDURES:

IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT– 113.40(b)(1))*

IS THE SENSOR BULB POSITIONED SO THAT IT EXTENDS DIRECTLY INTO THE WATER A MINIMUM OF AT LEAST 2 INCHES WITHOUT A SEPARABLE WELL OR SLEEVE AND IS BENEATH THE SURFACE OF THE WATER DURING THE COMPLETE PROCESS? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

ON HORIZONTAL RETORTS, IS THE MIG THERMOMETER INSERTED DIRECTLY INTO THE RETORT SHELL IN THE SIDE AT THE CENTER? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

EXPLAIN WHERE AND HOW THE MIG IS POSITIONED:

IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

TEMERATURE RECORDING DEVICE (113.40(b)(2))

IS THE RETORT EQUIPPED WITH A TEMPERATURE RECORDING DEVICE? ..... Yes ☐ No ☐

TYPE OF TEMPERATURE RECORDER ..... Round Circular Chart ☐ Strip Chart ☐ Other ☐

IF OTHER, DESCRIBE:

DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113? ..... Yes ☐ No ☐

(GRADUATIONS ON THE TEMPERATURE-RECORDING CHART SHALL NOT EXCEED 2°F(1°C) WITHIN A RANGE OF 10°F(5.5°C) OF THE PROCESSING TEMPERATURE. EACH CHART SHALL HAVE A WORKING SCALE OF NOT MORE THAN 55°F/IN.(12°C/CM) WITHIN A RANGE OF 20°F(10°C) OF THE PROCESSING TEMPERATURE .)

IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS NEARLY AS POSSIBLE WITH BUT NOT HIGHER THAN THE KNOWN ACCURATE MERCURY-IN-GLASS THERMOMETER DURING THE PROCESSING PERIOD? ..... Yes ☐ No ☐

(SHALL REQUIREMENT – NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MERCURY-IN-GLASS THERMOMETER AND WHICH READING IS HIGHER.)

IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUSTMENTS? ..... Yes ☐ No ☐

*(A MEANS OF PREVENTING UNAUTHORIZED CHANGES IN ADJUSTMENTS **SHALL** BE PROVIDED. A LOCK OR NOTICE FROM MANAGEMENT STATING "ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS" & POSTED AT OR NEAR THE RECORDING DEVICE IS A SATISFACTORY MEANS FOR PREVENTING UNAUTHORIZED CHANGES.)*

IS THE CHART DRIVE TIMING MECHANISM ACCURATE? ..... Yes ☐ No ☐

IF NO, EXPLAIN:

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER TO FUNCTION AS A RECORDING/CONTROLLING INSTRUMENT? ..... Yes ☐ No ☐

FOR VERTICAL STILL RETORTS EQUIPPED WITH A TEMPERATURE RECORDING/CONTROLLING DEVICE, IS THE TEMPERATURE SENSOR PROBE LOCATED AT THE BOTTOM OF THE RETORT BELOW THE LOWEST CRATE SUPPORT SO STEAM DOES NOT STRIKE IT DIRECTLY? ..... Yes ☐ No ☐

(SHALL REQUIREMENT)

FOR RETORTS OTHER THAN VERTICAL STILL RETORTS EQUIPPED WITH A RECORDING/CONTROLLING INSTRUMENT, IS THE RECORDING THERMOMETER BULB LOCATED ADJACENT TO THE BULB OF THE MERCURY-IN-GLASS THERMOMETER?

Yes ☐ No ☐

*(**SHOULD** REQUIREMENT – 113.40(b)(2))*

FOR HORIZONTAL STILL RETORTS EQUIPPED WITH A TEMPERATURE RECORDING/CONTROLLING DEVICE, IS THE TEMPERATURE RECORDING/CONTROLLING BULB LOCATED BETWEEN THE WATER SURFACE AND THE HORIZONTAL PLANE PASSING THROUGH THE CENTER OF THE RETORT SO THERE IS NO DIRECT STEAM IMPINGEMENT ON THE CONTROL BULB? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

PRESSURE GAGE (113.40(b)(3)(i))

IF A PRESSURE GAGE IS PRESENT, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

PRESSURE RELIEF VALVE (113.40(b)(3)(ii))

IS THE RETORT EQUIPPED WITH AN ADJUSTABLE PRESSURE RELIEF OR CONTROL VALVE INSTALLED IN THE OVERFLOW LINE? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

STEAM CONTROLLER (113.40(b)(4))

IS THE RETORT EQUIPPED WITH AN AUTOMATIC STEAM CONTROL VALVE? ..... Yes ☐ No ☐

*(EACH RETORT **SHALL** BE EQUIPPED WITH AN AUTOMATIC STEAM CONTROLLER TO MAINTAIN THE RETORT TEMPERATURE.)*

IS THE CONTROLLER COMBINED WITH A TEMPERATURE RECORDER TO FUNCTION AS A RECORDING/CONTROLLING INSTRUMENT? ..... Yes ☐ No ☐

IF THE TEMPERATURE (STEAM) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER TO ASSURE A SUPPLY OF CLEAN, DRY AIR? ..... Yes ☐ No ☐

(AIR OPERATED TEMPERATURE CONTROLLERS SHOULD HAVE ADEQUATE FILTER SYSTEMS TO ASSURE A SUPPLY OF CLEAN, DRY AIR, 113.40(b)(2).)

REPORT THE **MANUFACTURER**, **SIZE**, **MODEL** AND **TYPE** OF AUTOMATIC STEAM CONTROL VALVE:

STEAM INTRODUCTION (113.40(b)(5))

IS STEAM DISTRIBUTED IN THE BOTTOM OF THE RETORT? ..... Yes ☐ No ☐

(STEAM SHALL BE DISTRIBUTED IN THE BOTTOM OF THE RETORT IN A MANNER ADEQUATE TO PROVIDE UNIFORM HEAT DISTRIBUTION THROUGHOUT THE RETORT.)

FOR HORIZONTAL STILL RETORTS, IS THERE A STEAM DISTRIBUTION PIPE THAT RUNS THE LENGTH OF THE BOTTOM OF THE RETORT WITH PERFORATIONS DISTRIBUTED UNIFORMLY ALONG THE UPPER PART OF THE PIPE? .... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

DESCRIBE THE SHAPE AND DIMENSIONS OF THE STEAM SPREADER PIPE:

STACKING EQUIPMENT AND CONTAINER POSITION (113.40(b)(7))

ARE CRATES, TRAYS, ETC. FOR HOLDING CONTAINERS MADE OF STRAP IRON OR OTHER ADEQUATELY PERFORATED MATERIAL? ..... Yes ☐ No ☐

ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS? ..... Yes ☐ No ☐

ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POSITIONING FLEXIBLE CONTAINERS DESIGNED AND EMPLOYED TO INSURE EVEN CIRCULATION OF HEATING MEDIUM AROUND ALL CONTAINERS? ..... Yes ☐ No ☐

DRAIN LINE AND VALVE (113.40(b)(8))

ARE SCREENS USED OVER ALL DRAIN OPENINGS TO PREVENT CLOGGING OF DRAINS? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

IS THE DRAIN LINE VALVE WATER TIGHT AND NON-CLOGGING? ..... Yes ☐ No ☐

WATER LEVEL INDICATOR (113.40(b)(9))

DOES WATER COVER THE TOP LAYER OF CONTAINERS IN THE RETORT BASKETS DURING THE ENTIRE COME-UP TIME AND PROCESSING PERIOD? ..... Yes ☐ No ☐

DOES WATER COVER THE TOP LAYERS OF CONTAINERS DURING THE COOLING PERIOD? ..... Yes ☐ No ☐

*(WATER **SHALL** COVER THE TOP LAYER OF CONTAINERS DURING THE ENTIRE COME-UP TIME AND PROCESSING PERIOD AND **SHOULD** COVER THE TOP LAYER DURING THE COOLING PERIODS – 113.40(b)(9).)*

IS THERE A MEANS TO DETERMINE THE WATER LEVEL IN THE RETORT DURING OPERATION? ..... Yes ☐ No ☐

IF YES, WHAT MONITORING DEVICES ARE USED? ..... Gage ☐ Sight-glass ☐ Glass ☐ Petcock ☐ Other ☐

IF OTHER, EXPLAIN TYPE:

IF NO MONITORING DEVICES, EXPLAIN:

(THERE SHALL BE A MEANS OF DETERMINING THE WATER LEVEL IN THE RETORT DURING OPERATION.)

DOES THE OPERATOR CHECK AND RECORD THE WATER LEVEL AT INTERVALS SUFFICIENT TO ENSURE ITS ADEQUACY?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

PROCESSING WATER

IS THE PROCESSING WATER HEATED IN A SEPARATE VESSEL AND THEN INTRODUCED INTO THE PROCESSING VESSEL?

Yes ☐ No ☐

WAS THE TEMPERATURE OF THE PREHEATED WATER TAKEN INTO CONSIDERATION DURING TEMPERATURE DISTRIBUTION STUDIES? ..... Yes ☐ No ☐

DOES THE FIRM CONTROL THE PREHEATING OF PROCESS WATER AS CRITICAL TO THE THERMAL PROCESS?

Yes ☐ No ☐

AIR SUPPLY AND CONTROLS (113.40(b)(10))

IS AIR SUPPLIED TO THE RETORTS DURING THE COME-UP, PROCESSING AND COOLING PERIODS TO PROMOTE CIRCULATION OF WATER AND TEMPERATURE DISTRIBUTION? ..... Yes ☐ No ☐

IF YES, IS THE AIR INTRODUCED AT THE PROPER PRESSURE AND RATE? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.40(b)(10)(i))*

IS THE COMPRESSED AIR SUPPLIED TO THE RETORT CONTROLLED BY AN AUTOMATIC PRESSURE CONTROL UNIT?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.40(b)(10)(i))*

IS THE AIR SUPPLY LINE EQUIPPED WITH A CHECK VALVE TO PREVENT WATER FROM ENTERING THE SYSTEM?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.40(b)(10)(i))*

HAS THE ADEQUACY OF THE AIR OR WATER CIRCULATION FOR UNIFORM HEAT DISTRIBUTION WITHIN THE RETORT BEEN ESTABLISHED IN ACCORDANCE WITH PROCEDURES RECOGNIZED BY A COMPETENT PROCESS AUTHORITY?

Yes ☐ No ☐

ARE RECORDS OF THE ESTABLISHMENT OF UNIFORM HEAT DISTRIBUTION KEPT ON FILE? ..... Yes ☐ No ☐

(SHALL REQUIREMENT) – 113.40(b)(10)(i))

IF AIR IS USED TO PROMOTE WATER CIRCULATION IN THE RETORT, IS IT INTRODUCED INTO THE STEAM LINE AT A POINT BETWEEN THE RETORT AND THE STEAM CONTROL VALVE AT THE BOTTOM OF THE RETORT? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.40(b)(10)(i))*

WHEN A WATER CIRCULATING SYSTEM IS USED FOR HEAT DISTRIBUTION, IS IT INSTALLED IN SUCH A MANNER THAT WATER WILL BE DRAWN FROM THE BOTTOM OF THE RETORT THROUGH A SUCTION MANIFOLD AND DISCHARGED THROUGH A SPREADER WHICH EXTENDS THE LENGTH OF THE TOP OF THE RETORT? ..... Yes ☐ No ☐ N/A ☐

*(**SHALL** REQUIREMENT – 113.40(b)(10)(ii))*

FOR WATER CIRCULATING SYSTEMS, ARE THE HOLES IN THE WATER SPREADER UNIFORMLY DISTRIBUTED AND DO THEY HAVE AN AGGREGATE AREA NOT GREATER THAN THE CROSS-SECTION AREA OF THE OUTLET LINE FROM THE PUMP?

Yes ☐ No ☐ N/A ☐

(SHALL/SHOULD REQUIREMENT) – 113.40(b)(10)(ii))

ARE SUCTION OUTLETS PROTECTED WITH NONCLOGGING SCREENS TO KEEP DEBRIS FROM ENTERING THE CIRCULATING SYSTEM? ..... Yes ☐ No ☐

(SHALL REQUIREMENT) – 113.40(b)(10)(ii))

IS THE WATER PUMP EQUIPPED WITH A PILOT LIGHT OR OTHER SIGNALING DEVICE TO WARN THE OPERATOR WHEN IT IS NOT RUNNING? ..... Yes ☐ No ☐

(SHALL REQUIREMENT – 113.40(b)(10)(ii))

IS AN ALTERNATE METHOD OF WATER CIRCULATION USED? ..... Yes ☐ No ☐

(113.40(b)(10)(ii))

IF YES, HAS THE METHOD BEEN ESTABLISHED BY A COMPETENT PROCESS AUTHORITY? ..... Yes ☐ No ☐

DESCRIBE THE ALTERNATE METHOD:

COOLING WATER SUPPLY

FOR VERTICAL STILL RETORTS, IS THE COOLING WATER INTRODUCED AT THE TOP OF THE RETORT BETWEEN THE WATER AND CONTAINER LEVELS? ..... Yes ☐ No ☐ N/A ☐

*(**SHOULD** REQUIREMENT - 113.40(b)(11))*

FOR HORIZONTAL RETORTS, IS THE COOLING WATER INTRODUCED INTO THE SUCTION SIDE OF THE PUMP?

Yes ☐ No ☐

*(**SHOULD** REQUIREMENT 113.40(b)(11))*

IS THE WATER-COOLING LINE EQUIPPED WITH A CHECK VALVE? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT – 113.40(b)(11))*

RETORT HEADSPACE

IS HEADSPACE, NECESSARY TO CONTROL THE AIR PRESSURE, MAINTAINED BETWEEN THE WATER LEVEL AND THE TOP OF THE RETORT SHELL? ..... Yes ☐ No ☐

(SHOULD REQUIREMENT) – 113.40(b)(12))